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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,914	07/03/2003	Eyal Talor	CS-120	5597
7590 08/19/2004			EXAMINER	
SHERMAN & SHALLOWAY 413 North Washington Street Alexandria, VA 22314			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 08/19/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/611,914	<b>Applicant(s)</b> TALOR, EYAL	
	<b>Examiner</b> Gary B. Nickol Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 28-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 24-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Re: Talor, E.

Date of priority: 07/03/2003

The Election filed 03/09/04 in response to the Office Action of 02/27/04 is acknowledged and has been entered.

Applicant's election with traverse of Group III, claims 24-27 is acknowledged. The traversal is on the ground(s) that Groups 3-17 are all drawn to the same composition as claims 24-41 and further contain the limitations of claim 24. Applicants further note that restrictions should never be made where the claims of an application define the same essential characteristics of a single disclosed embodiment of the invention. Applicants further note that the additional rule that claims alleged to be drawn to different species must contain mutually exclusive limitations defining those allegedly different species. These arguments have been carefully considered but are not found persuasive. The compositions of cytokines were held to be independent and or distinct (not species of each other) for the reasons of record set forth previously. And, though, the limitations of claim 24 are recited throughout, the inclusion of different molecule imparts functional and chemical distinctness providing for independent compositions.

Further, although the inventions are classified somewhat similarly, the classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

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Claims 24-27 currently under consideration.

Claims 1-23 and 28-41 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

### ***Specification***

The amendment filed 03-09-04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments to paragraphs 15 and 26 of the specification (those that specifically alter numerical ranges) are not supported by the specification as originally filed. With the exception of the apparent typographical error wherein applicants proposed to correct recitation of “41” to “411”, the remaining changes to the ratios are not supported in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Objections***

Claims 25 and 27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The TNF- $\alpha$  to IL-2 range of 7.7 to 11.3 does not include the limitations of the independent claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hadden, J. (US Patent No. 5,698,194, December 1997, IDS).

US 5698194 ('194) teaches a serum-free and mitogen free (column 5, lines 1-5) cytokine mixture *comprising* specific ratios of cytokines that encompass the following claimed ranges:

IL-1 $\beta$  to IL-2 at a ratio range of 0.4 - 1.5, alternatively 0.6 to 1.5 (Claim 25,27)

TNF- $\alpha$  to IL-2 at a ratio range of 3.2 – 10.9, alternatively 7.7 to 11.3

IFN- $\gamma$  to IL-2 at a ratio range of 1.5 – 10.9, alternatively 4.9 to 7.1

GM-CSF to IL-2 at a ratio range of 2.2 – 4.8, alternatively 3.5 to 4.5.

For example, (column 7, line 23) GM-CSF ranges from 10-1500 pg/ml and IL-2 ranges from 100-500 units/ml. Thus, if the average amount of IL-2 is approx. 300 units/ml, then the ratio of GM-CSF to IL-2 (10/300 and 1500/300) is .033 to 5 which encompasses the claimed ranges. Assuming the above, the prior art teaches the following ranges:

IL-1 to IL-2 is .033 to 6.7

TNF- $\alpha$  to IL-2 is .167 to 50

IFN- $\gamma$  to IL-2 is .167 to 50

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GM-CSF to IL-2 is .033 to 5

The reference further teaches pharmaceutical compositions of the above cytokine mixtures (column 10, line 10). Absent evidence to the contrary, it is assumed for examination purposes that the IL-1 used by the prior art was equivalent to and or comprised equivalent ratios of IL-1 $\beta$  (see Applicant's comments, "Discussion of Newly Cited References", 03/09/04, page 7, line 7).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

GBN  
August 12, 2004

A handwritten signature in black ink, reading "Gary B. Nickol". The signature is written in a cursive, flowing style with a large initial "G" and a long, sweeping underline.

**GARY NICKOL**  
**PRIMARY EXAMINER**